CHAIRMAN FRANK PALLONE, JR.

#### MEMORANDUM

February 19, 2021

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "Pathway to Protection: Expanding Availability of COVID-19

Vaccines"

On <u>Tuesday, February 23, 2021, at 10:30 a.m.</u> (EST) via Cisco WebEx online video <u>conferencing</u>, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "Pathway to Protection: Expanding Availability of COVID-19 Vaccines." The hearing will examine manufacturers' ongoing efforts to develop and expand production of coronavirus disease of 2019 (COVID-19) vaccines in the United States.

### I. BACKGROUND ON COVID-19 IN THE UNITED STATES

On January 21, 2020, the Centers for Disease Control and Prevention (CDC) announced the first reported case of COVID-19 in the United States. COVID-19 can be asymptomatic or cause a range of symptoms, which are typically more severe among older adults and people with underlying medical conditions, and has disproportionately affected people of color. Former Secretary of Health and Human Services (HHS) Alex Azar declared the disease a public health emergency on January 31, 2020, and former President Trump declared the outbreak a national emergency on March 13, 2020. To date, more than 27 million Americans have contracted

<sup>&</sup>lt;sup>1</sup> Centers for Disease Control and Prevention, *First Travel-related Case of 2019 Novel Coronavirus Detected in United States* (Jan. 21, 2020) (press release).

<sup>&</sup>lt;sup>2</sup> Centers for Disease Control and Prevention, *Things to Know about the COVID-19 Pandemic* (www.cdc.gov/coronavirus/2019-ncov/your-health/need-to-know.html) (accessed Feb. 10, 2021); Centers for Disease Control and Prevention, *COVID-19 Hospitalization and Death by Race/Ethnicity* (www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html) (accessed Feb. 10, 2021).

<sup>&</sup>lt;sup>3</sup> U.S. Department of Health and Human Services, *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (Jan. 31, 2020) (press release); Presidential Proclamation No. 9994, 85 Fed. Reg. 15337 (Mar. 18, 2020).

# II. FEDERAL GOVERNMENT ACTION TO ADDRESS THE COVID-19 PANDEMIC

Since the COVID-19 outbreak began in the United States, Congress has provided more than \$60 billion to facilitate the development, production, and distribution of COVID-19 medical countermeasures, including vaccines. A safe and effective COVID-19 vaccine is an essential tool to contain the pandemic. The Food and Drug Administration (FDA) has granted two Emergency Use Authorizations (EUA) for COVID-19 vaccines, developed by Pfizer and Moderna, both of which require the administration of two doses for full vaccination. According to CDC, as of February 14, 2021, the federal government had distributed 70 million vaccine doses to states, territories, and tribes. A total of 55.2 million doses have been administered, of which 15 million were second-dose shots.

On May 15, 2020, the Trump Administration announced Operation Warp Speed (OWS), a partnership among HHS, the Department of Defense, private companies, and other federal agencies aimed at accelerating "the development, manufacturing, and distribution of COVID-19 vaccines" and other medical countermeasures. <sup>10</sup> OWS initially aimed to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021, though OWS later reduced that goal to 20 million doses by the end of 2020. <sup>11</sup> OWS officials attributed the initially low

<sup>&</sup>lt;sup>4</sup> Centers for Disease Control and Prevention, *United States COVID-19 Cases and Deaths by State* (www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html) (accessed Feb. 15, 2021).

<sup>&</sup>lt;sup>5</sup> Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, Pub. L. 116-136; Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. 116-123; Consolidated Appropriations Act, 2021, Pub. L. 116-260.

<sup>&</sup>lt;sup>6</sup> Centers for Disease Control and Prevention, *Benefits of Getting Vaccinated* (www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html) (accessed Feb. 10, 2021).

<sup>&</sup>lt;sup>7</sup> U.S. Food and Drug Administration, *COVID-19 Vaccines* (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines) (accessed Feb. 16, 2021).

<sup>&</sup>lt;sup>8</sup> Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (https://covid.cdc.gov/covid-data-tracker/#vaccinations) (accessed Feb. 15, 2021).

<sup>&</sup>lt;sup>9</sup> *Id*.

<sup>&</sup>lt;sup>10</sup> U.S. Department of Health and Human Services, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'* (May 15, 2020) (press release).

<sup>&</sup>lt;sup>11</sup> U.S. Department of Defense, *Operation Warp Speed on Track for End-of-Year Vaccine Delivery* (Aug. 12, 2020) (press release); U.S. Department of Defense, *Operation Warp Speed Leaders Say 20 Million COVID-19 Vaccines May Be Available This Month* (Dec. 3, 2020) (press release).

rates of vaccine administration to a combination of anticipated implementation hurdles. <sup>12</sup> State leaders, meanwhile, pointed to limited supply of doses, delayed funding to support vaccine distribution and administration programs, overburdened staff and hospital capacity, and limited notice of weekly dose allocations from the federal government to explain the slow pace of vaccination. <sup>13</sup> States also noted challenges with the rollout of the federal pharmacy partnership program, which relies on retail pharmacies to vaccinate residents and staff of long-term care facilities. <sup>14</sup>

President Biden has committed to getting 100 million COVID-19 vaccine doses administered in his first 100 days in office, and recently estimated that 1.5 million shots per day can be administered across the country in the coming weeks. To achieve this goal, the President has proposed \$20 billion for a national COVID-19 vaccine program to speed the distribution and administration of COVID-19 vaccines, including funding for distribution to underserved communities. On January 21, 2021, President Biden released a national COVID-19 strategy and issued 10 executive orders for COVID-19 response priorities. The President also invoked the Defense Production Act in an effort to increase the supply of materials necessary for COVID-19 vaccination, such as syringes that can maximize the amount of vaccine extracted from vials.

The Biden Administration has begun establishing vaccine centers at large venues and mobilizing federal personnel, including more than 1,000 active-duty service members, and has announced that it would reimburse states for using the National Guard to assist with

<sup>&</sup>lt;sup>12</sup> Shots are slow to reach arms as Trump administration leaves final steps of mass vaccination to beleaguered states, Washington Post (Dec. 30, 2020); Here's Why Distribution of the Vaccine Is Taking Longer Than Expected, New York Times (Jan. 1, 2021).

<sup>&</sup>lt;sup>13</sup> Here's Why Distribution of the Vaccine Is Taking Longer Than Expected, New York Times (Jan. 1, 2021); CVS and Walgreens Under Fire for Slow Pace of Vaccination in Nursing Homes, Kaiser Health News (January 15, 2021); House Committee on Energy and Commerce, Hearing on No Time to Lose: Solutions to Increase COVID-19 Vaccinations in the States, 117th Cong. (Feb. 2, 2021).

<sup>&</sup>lt;sup>14</sup> *Id*.

<sup>&</sup>lt;sup>15</sup> 100M shots in the first 100 days: Biden unveils Covid priorities, introduces health team, NBC News (Dec. 8, 2020); Biden ups vaccine goal to 1.5 million shots a day, says vaccine to be widely available by spring, NBC News (Jan. 25, 2021).

<sup>&</sup>lt;sup>16</sup> Joe Biden's Covid-19 Vaccine Plan: How He Intends to Speed Up Distribution, Wall Street Journal (Jan. 21, 2021).

<sup>&</sup>lt;sup>17</sup> White House, National Strategy for the COVID-19 Response and Pandemic Preparedness (Jan. 21, 2021); Biden unveils national COVID strategy with slate of executive orders, CBS News (Jan. 21, 2021).

<sup>&</sup>lt;sup>18</sup> Wartime effort': Biden signs orders to fight the pandemic, Politico (Jan. 21, 2021).

vaccinations.<sup>19</sup> Additionally, on January 26, 2021, the Biden Administration told states, territories, and tribes it would begin projecting state allocations of vaccine doses three weeks ahead of shipment.<sup>20</sup> Since then, state vaccine supplies have increased to 13.5 million doses each week.<sup>21</sup> The Biden Administration has also mobilized a federal partnership program with retail pharmacies, which receive a separate allocation of two million doses per week.<sup>22</sup> Further, on February 9, 2021, the Biden Administration announced it would begin shipping one million COVID-19 vaccine doses per week directly to community health centers to serve marginalized populations.<sup>23</sup>

## III. COMPANIES INVOLVED IN COVID-19 VACCINE DEVELOPMENT AND PRODUCTION

Multiple companies have developed COVID-19 vaccines or vaccine candidates for use in the United States. The Committee has invited five companies to testify—Pfizer, Moderna, Johnson & Johnson, AstraZeneca, and Novavax—all of which have supply agreements with the U.S. government.

## A. Pfizer

Pfizer is a global biopharmaceutical company headquartered in New York, New York, and was the first company to receive an EUA for a COVID-19 vaccine in the United States. <sup>24</sup> On March 16, 2020, Pfizer announced it had reached a letter of intent with German biotechnology firm BioNTech regarding the co-development and distribution of a potential messenger RNA (mRNA)-based COVID-19 vaccine. <sup>25</sup> Although Pfizer did not accept federal funds to develop or manufacture its vaccine, on July 22, 2020, the federal government entered into a purchase agreement with Pfizer for 100 million doses, with the option to purchase up to

<sup>&</sup>lt;sup>19</sup> Biden unveils national COVID strategy with slate of executive orders, CBS News (Jan. 21, 2021); Biden administration deploys more than 1,000 active-duty troops to aid vaccination efforts, Politico (Feb. 5, 2021).

<sup>&</sup>lt;sup>20</sup> Biden announces purchase of 200M vaccine doses, CNN (Jan. 26, 2021).

<sup>&</sup>lt;sup>21</sup> U.S. vaccine supply is increasing to 13.5 million doses per week, Bloomberg (Feb. 16, 2021).

<sup>&</sup>lt;sup>22</sup> White House, FACT SHEET: President Biden Announces Increased Vaccine Supply, Initial Launch of the Federal Retail Pharmacy Program, and Expansion of FEMA Reimbursement to States (Feb. 2, 2021) (press release).

<sup>&</sup>lt;sup>23</sup> White House, FACT SHEET: President Biden Announces Community Health Centers Vaccination Program to Launch Next Week and Another Increase in States, Tribes, & Territories' Vaccine Supply (Feb. 9, 2021).

<sup>&</sup>lt;sup>24</sup> Pfizer, SEC Form 10-K (Feb. 27, 2020); Pfizer, *Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19* (Dec. 11, 2020) (press release).

<sup>&</sup>lt;sup>25</sup> Pfizer, *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine* (Mar. 16, 2020) (press release).

500 million more doses, if the vaccine were approved or authorized by FDA.<sup>26</sup> On November 18, 2020, Pfizer announced that its vaccine was shown to be 95 percent effective in preventing symptomatic COVID-19.<sup>27</sup> On December 11, 2020, FDA issued an EUA for Pfizer's two-dose COVID-19 vaccine to be administered 21 days apart.<sup>28</sup> On December 23, 2020, the federal government ordered an additional 100 million doses, with 70 million doses due for delivery by June 30, 2021, and the remainder by July 31, 2021.<sup>29</sup> On February 11, 2021, President Biden announced that the federal government had purchased an additional 100 million doses from Pfizer, which are expected to be delivered by July 31, 2021, bringing Pfizer's total U.S. commitment to 300 million doses.<sup>30</sup> Pfizer expects to supply up to two billion doses globally by the end of 2021.<sup>31</sup> As of January 31, 2021, Pfizer reported it had shipped more than 29 million doses across the country.<sup>32</sup>

#### B. Moderna

Moderna is a clinical stage biotechnology company based in Cambridge, Massachusetts, working on mRNA therapeutics and vaccines, including the first COVID-19 vaccine candidate to enter clinical trials in the United States.<sup>33</sup> The Biomedical Advanced Research and Development Authority (BARDA) awarded Moderna up to \$483 million in April 2020 and another \$53 million in May 2020 to accelerate the development of and increase manufacturing capacity for the

<sup>&</sup>lt;sup>26</sup> Pfizer, Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-Based Vaccine Candidate Against SARS-COV-2 (July 22, 2020) (press release).

<sup>&</sup>lt;sup>27</sup> Pfizer, *Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints* (Nov. 18, 2020) (press release).

<sup>&</sup>lt;sup>28</sup> U.S. Food and Drug Administration, *Pfizer-BioNTech COVID-19 Vaccine* (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine) (accessed Feb. 11, 2021).

<sup>&</sup>lt;sup>29</sup> Pfizer, *Pfizer and BioNTech to Supply the U.S. with 100 Million Additional Doses of COVID-19 Vaccine* (Dec. 23, 2020) (press release).

<sup>&</sup>lt;sup>30</sup> U.S. Department of Health and Human Services, *Biden Administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna* (Feb. 11, 2021) (press release).

<sup>&</sup>lt;sup>31</sup> BioNTech lifts 2021 COVID-19 vaccine output target to 2 billion doses, Reuters (Jan. 11, 2021).

<sup>&</sup>lt;sup>32</sup> Pfizer plans to deliver 200 million doses of Covid vaccine to U.S. by May, sooner than expected, CNBC (Feb. 2, 2021).

<sup>&</sup>lt;sup>33</sup> Moderna, Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (Mar. 16, 2020) (press release); First Patient Dosed in Moderna's COVID-19 Vaccine Trial, Bio Space (Mar. 16, 2020).

company's vaccine candidate.<sup>34</sup> On November 30, 2020, Moderna announced that its vaccine was shown to be approximately 94 percent effective in preventing symptomatic COVID-19.<sup>35</sup> On December 18, 2020, FDA issued an EUA for Moderna's two-dose vaccine to be administered 28 days apart.<sup>36</sup> The federal government's initial supply agreement with Moderna was for 100 million doses with the option to purchase up to an additional 400 million doses.<sup>37</sup> On December 11, 2020, the federal government exercised the first option for an additional 100 million doses, to be delivered by June 30, 2021.<sup>38</sup> On February 11, 2021, President Biden announced that the federal government had exercised another option to purchase an additional 100 million doses from Moderna, which are expected to be delivered by July 31, 2021, bringing Moderna's total U.S. commitment to 300 million doses.<sup>39</sup> Moderna expects to supply between 600 million and one billion doses of its vaccine globally in 2021.<sup>40</sup> As of February 16, 2021, Moderna had supplied the U.S. government with 45.4 million doses.<sup>41</sup>

## C. Johnson & Johnson

Johnson & Johnson is an American multinational corporation headquartered in New Brunswick, New Jersey, that develops medical devices, pharmaceuticals, and consumer products.<sup>42</sup> On March 30, 2020, Janssen Pharmaceutical Companies, a subsidiary of Johnson &

<sup>&</sup>lt;sup>34</sup> Moderna, *Moderna Announces Award from U.S. Government Agency BARDA for Up to* \$483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (Apr. 16, 2020) (press release); U.S. Department of Health and Human Services, *COVID-19 Medical Countermeasure Portfolio* (https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx) (accessed Feb. 10, 2021).

<sup>&</sup>lt;sup>35</sup> Moderna, *Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization* (Nov. 30, 2020) (press release).

<sup>&</sup>lt;sup>36</sup> U.S. Food and Drug Administration, *Moderna COVID-19 Vaccine* (www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine) (accessed Feb. 10, 2021).

<sup>&</sup>lt;sup>37</sup> Moderna, Moderna Announces Supply Agreement with U.S. Government for Initial 100 Million Doses of mRNA Vaccine Against COVID-19 (mRNA-1273) (Aug. 11, 2020) (press release).

<sup>&</sup>lt;sup>38</sup> Moderna, U.S. Government Exercises 1<sup>st</sup> Option for Additional 100 Million Doses of Moderna's COVID-19 Vaccine Candidate (Dec. 11, 2020) (press release).

<sup>&</sup>lt;sup>39</sup> *See* note 30.

<sup>&</sup>lt;sup>40</sup> Moderna, *Moderna Provides COVID-19 Vaccine Supply Update* (Jan. 26, 2021) (press release).

<sup>&</sup>lt;sup>41</sup> Moderna, *Moderna Provides COVID-19 Vaccine Supply Update* (Feb. 16, 2021) (press release).

<sup>&</sup>lt;sup>42</sup> *Johnson & Johnson Profile*, Market Watch (www.marketwatch.com/investing/stock/jnj/profile) (accessed Feb. 12, 2021).

Johnson, announced the selection of a lead COVID-19 vaccine candidate, which uses a modified adenovirus, along with two back-ups. <sup>43</sup> BARDA awarded the company \$456 million to support development of the lead vaccine candidate and secure an initial 100 million doses for the federal government. <sup>44</sup> On January 29, 2021, Janssen announced that its vaccine was shown to be 66 percent effective in preventing moderate to severe COVID-19. <sup>45</sup> On February 4, 2021, Janssen submitted an EUA application for its vaccine candidate to FDA, which will hold a public meeting of the Vaccine and Related Biologics Products Advisory Committee on February 26, 2021, to discuss authorization of the vaccine candidate. <sup>46</sup> The Janssen vaccine is administered as a single dose. <sup>47</sup> The company's stated goal is to supply more than one billion doses of its vaccine globally through 2021, and it has committed to bringing a vaccine to the public on a not-for-profit basis for emergency pandemic use. <sup>48</sup>

#### D. AstraZeneca

AstraZeneca is a biopharmaceutical company based in the United Kingdom focused on developing medicines to treat oncology, cardiovascular, renal and metabolism, and respiratory and immunology diseases. On April 30, 2020, AstraZeneca announced an agreement with the University of Oxford for the global development and distribution of the University's potential recombinant adenovirus vaccine for COVID-19. The Trump Administration announced a collaboration with AstraZeneca on May 21, 2020, to produce at least 300 million doses of this

<sup>&</sup>lt;sup>43</sup> Johnson & Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use (Mar. 30, 2020) (press release); Johnson & Johnson To Begin Human Trials for Coronavirus Vaccine in Late July, Earlier than Expected, CNBC (June 10, 2020).

<sup>&</sup>lt;sup>44</sup> U.S. Department of Health and Human Services, *HHS*, *DOD Collaborate With Johnson & Johnson to Produce Millions of COVID-19 Investigational Vaccine Doses* (June 16, 2020).

<sup>&</sup>lt;sup>45</sup> Johnson & Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial (Jan. 29, 2021) (press release).

<sup>&</sup>lt;sup>46</sup> U.S. Food and Drug Administration, FDA Announces Advisory Committee Meeting to Discuss Janssen Biotech Inc.'s COVID-19 Vaccine Candidate (Feb. 4, 2021) (press release).

<sup>&</sup>lt;sup>47</sup> National Institutes of Health, *Janssen Investigational COVID-19 Vaccine: Interim Analysis of Phase 3 Clinical Data Released* (Jan. 29, 2021) (press release).

<sup>&</sup>lt;sup>48</sup> Johnson & Johnson & Johnson & Johnson Announces Agreement with U.S. Government for 100 Million Doses of Investigational COVID-19 Vaccine (Aug. 5, 2020) (press release).

<sup>&</sup>lt;sup>49</sup> AstraZeneca, *AstraZeneca and Oxford University Announce Landmark Agreement for COVID-19 Vaccine* (Apr. 30, 2020) (press release).

<sup>&</sup>lt;sup>50</sup> *Id*.

vaccine in the United States.<sup>51</sup> Through OWS, AstraZeneca was awarded \$1.2 billion from BARDA to support development and production of this vaccine candidate.<sup>52</sup> AstraZeneca has received authorization for its vaccine from the World Health Organization but is awaiting results from a large U.S.-based trial before submitting an EUA to FDA.<sup>53</sup> AstraZeneca announced it would supply up to three billion doses of its vaccine globally on a rolling basis, pending authorization from health authorities.<sup>54</sup>

## E. Novavax

Novavax is a clinical-stage biotechnology company based in Gaithersburg, Maryland, that develops novel vaccines to prevent serious infectious diseases. On February 26, 2020, Novavax announced that it had developed a protein-based COVID-19 vaccine candidate. In July 2020, BARDA awarded Novavax a \$1.6 billion contract to conduct its Phase 3 clinical trials in the United States, as well as to secure the purchase of 100 million doses. Novavax is continuing its Phase 3 trials in the United States, and if authorized, expects to supply up to 150 million doses monthly of its COVID-19 vaccine globally starting in May or June 2021.

## IV. KEY CHALLENGES AND OPPORTUNITIES FOR THE VACCINATION PROGRAM

Although the rapid development of two FDA-authorized vaccines—with potentially three more on the horizon—has exceeded most expectations, the lack of available doses to meet the demand remains the biggest challenge. While current projections should provide enough doses

<sup>&</sup>lt;sup>51</sup> U.S. Department of Health and Human Services, *Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to Be Available Beginning in October* (May 21, 2020) (press release).

<sup>&</sup>lt;sup>52</sup> *Id*.

<sup>&</sup>lt;sup>53</sup> WHO approves AstraZeneca/Oxford COVID-19 vaccine for emergency use, Reuters (Feb. 15, 2021); Coronavirus update: AstraZeneca expects Phase 3 results soon; WHO warns against vaccine nationalism, Yahoo (Feb. 11, 2021).

<sup>&</sup>lt;sup>54</sup> AstraZeneca, *AstraZeneca's COVID-19 vaccine authorised for emergency supply in the UK* (Dec. 30, 2020) (press release).

<sup>&</sup>lt;sup>55</sup> Novavax, *Novavax Announces Development of Novel COVID-19 Vaccine* (Feb. 26, 2020) (press release).

<sup>&</sup>lt;sup>56</sup> *Id*.

<sup>&</sup>lt;sup>57</sup> U.S. Department of Health and Human Services, *HHS, DOD Collaborate with Novavax to Produce Millions of COVID-19 Investigational Vaccine Doses in Commercial-Scale Manufacturing Demonstration Projects* (July 7, 2020) (press release).

<sup>&</sup>lt;sup>58</sup> Novavax, Novavax Announces Start of Rolling Review by Multiple Regulatory Authorities for COVID-19 Vaccine Authorization (Feb. 4, 2021) (press release); Novavax expects to produce 150 million vaccine doses per month as early as May: CEO, Reuters (Jan. 29, 2021).

to vaccinate all eligible Americans by the end of the summer, demand continues to outpace supply of the vaccine.<sup>59</sup>

Continued community spread and evolving variants present threats to controlling the pandemic. Two new variants of the virus are particularly concerning: the B.1.1.7 variant that emerged in the United Kingdom and the B.1.351 variant that emerged in South Africa. These two variants appear to spread more quickly than the common strain of the virus, increasing the number of cases and hospitalizations, and could become the predominant strain. Some companies are currently developing booster shots for the new variants in case the current vaccines do not provide sufficient protection. FDA is planning a rapid review process for these booster shots rather than the large-scale trials required for the initial authorization.

Many Americans who are more vulnerable to COVID-19 and its effects may be less likely to have access to or seek COVID-19 vaccines. According to CDC, the limited data available show that Black and Hispanic people are being vaccinated against COVID-19 at lower rates than white people in the United States, despite facing significantly higher rates of infection, hospitalization, and death. Public confidence in a COVID-19 vaccine also remains a challenge. Although overall public confidence increased in December 2020 after dramatic declines in the preceding months, some hospital and nursing home staff are reportedly turning down vaccinations. These trends underscore the need for a public health education and

<sup>&</sup>lt;sup>59</sup> Fauci: Vaccinations will help coronavirus variants from emerging, CNN, (Jan. 22, 2021).

 $<sup>^{60}</sup>$  *Id*.

<sup>&</sup>lt;sup>61</sup> Centers for Disease Control and Prevention, *New Variants of the Virus that Causes COVID-19* (https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html) (accessed Feb. 11, 2021).

<sup>62</sup> Id

<sup>&</sup>lt;sup>63</sup> See, e.g., As Virus Grows Stealthier, Vaccine Makers Reconsider Battle Plans, New York Times (Jan. 25, 2021); Pfizer working on booster shot to protect against COVID-19 variants, Reuters (Jan. 26, 2021).

<sup>&</sup>lt;sup>64</sup> U.S. FDA gearing up for rapid review of potential COVID-19 booster shots, Reuters (Feb. 4, 2021).

<sup>&</sup>lt;sup>65</sup> Centers for Disease Control and Prevention, *Demographic Characteristics of Persons Vaccinated During the First Month of the COVID-19 Vaccination Program* — *United States*, *December 14*, 2020–January 14, 2021 (Feb. 5, 2021) (MMWR 70(5); 174-177); Centers for Disease Control and Prevention, *Race, Ethnicity, and Age Trends in Persons Who Died from COVID-19* — *United States, May–August 2020* (Oct. 23, 2020) (MMWR 69(42); 1517–1521).

<sup>&</sup>lt;sup>66</sup> KFF, COVID-19 Vaccine Monitor: December 2020 (Jan. 15, 2021).

<sup>&</sup>lt;sup>67</sup> Centers for Disease Control and Prevention, Early COVID-19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program — United States, December 2020–January 2021 (Feb. 5, 2021) (MMWR 70(5);178–182).

communications campaign, as called for in President Biden's national strategy and as authorized by the Consolidated Appropriations Act of 2021. <sup>68</sup>

### V. WITNESSES

The following witnesses have been invited to testify:

## John Young

Group President, Chief Business Officer Pfizer

## **Dr. Stephen Hoge**

President Moderna

### **Dr. Richard Nettles**

Vice President of Medical Affairs, Janssen Pharmaceutical Companies Johnson & Johnson

#### Dr. Ruud Dobber

Executive Vice President and President, BioPharmaceuticals Business Unit AstraZeneca

### John Trizzino

Executive Vice President, Chief Commercial Officer, and Chief Business Officer Novavax, Inc.

 $<sup>^{68}</sup>$  Consolidated Appropriations Act, 2021, Pub. L. 116-260.